

105 CMR 143.000: STANDARDS GOVERNING CARDIAC REHABILITATION TREATMENT

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143.001: Purpose and Scope

St. 1985, c. 628 requires certain health insurance plans to provide benefits for the expense of cardiac rehabilitation treatment. St. 1985, c. 628 also provides that, in order to be included in such mandatory coverage, cardiac rehabilitation treatment must meet standards promulgated by the Commissioner of Public Health. The purpose of 105 CMR 143.000 is to set forth the standards which cardiac rehabilitation treatment must meet under St. 1985, c. 628. The standards are intended to prescribe the basic program components for cardiac rehabilitation, including the baseline characteristics of candidates for cardiac rehabilitation. They do not prescribe a set course of treatment to individual patients nor do they define the medical necessity of the treatment for individual patients. Those aspects of cardiac rehabilitation are properly in the realm of the patient's physician and the program's professional staff, as well as any additional standards which third party payors may set.

143.002: Authority

105 CMR 143.000 is adopted under the authority of St. 1985, c. 628.

143.003: Citation

105 CMR 143.000 shall be known and may be cited as 105 CMR 143.000: *Standards Governing Cardiac Rehabilitation Treatment*.

143.004: Definitions

Physician shall mean a doctor of medicine or doctor of osteopathy who is registered to practice medicine in Massachusetts pursuant to M.G.L. c. 112, § 2.

Registered Nurse shall mean an individual registered under M.G.L. c. 112, § 74.

143.005: General Requirements for Cardiac Rehabilitation Programs

For the purposes of St. 1985, c. 628, cardiac rehabilitation treatment must be provided by a "cardiac rehabilitation program" which meets the requirements set forth hereafter in 105 CMR 143.000.

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A "cardiac rehabilitation program" or "CRP" shall mean the Phase II and Phase III program components of a multiphasic program of medically necessary treatment that is designed to restore and maintain the individual with documented cardiovascular disease to optimal physiological and psychosocial health. Cardiac rehabilitation treatment shall be initiated within 26 weeks after the diagnosis of or an event related to cardiovascular disease. For the purposes of this section, event related to cardiovascular disease shall at a minimum include angioplasty, cardiovascular surgery and myocardial infarction.

Phase II shall mean the outpatient convalescent phase of a multiphasic cardiac rehabilitation program that begins subsequent to hospital discharge and usually extends for three to 12 weeks.

Phase III shall mean the outpatient phase of a multiphasic cardiac rehabilitation program that addresses multiple risk reduction, adjustment to illness and therapeutic exercise, follows the convalescent phase and usually extends for a period of 12 to 26 weeks.

For the purposes of 105 CMR 143.000, "cardiac rehabilitation program" does not include Phase I (the in-patient phase of a multiphasic cardiac rehabilitation program beginning at the time of the cardiac event and continuing until the time of hospital discharge) and Phase IV, (that phase of a multiphasic cardiac rehabilitation program that begins following completion of Phase III and is designed to maintain the patients' rehabilitated cardiovascular health).

143.006: Candidates for Cardiac Rehabilitation Programs

(A) All individuals shall enter the cardiac rehabilitation program through a referral from a physician responsible for the individual's care.

(B) Participants in the cardiac rehabilitation program shall be post-operative cardiovascular surgery patients, or shall have documented coronary artery disease verified by a positive exercise tolerance test, thallium scan or coronary angiography, or shall have a documented myocardial infarction.

(C) Each CRP shall develop written admission policies that clearly state admission criteria. Such policies shall specifically define contraindications to admission and shall be approved by the Medical Director.

(D) Each CRP shall develop written policies that clearly specify the conditions which exclude a patient from engaging in the therapeutic exercise. Such policies shall be approved by the Medical Director.

143.007: Administrative Records

(A) Each program shall maintain and have available current, complete, and accurate administrative records in a safe location.

(B) Administrative records shall include:

(1) Updated articles of organization and by-laws, partnership agreement or trust instrument, as appropriate. The documents shall specify the organizational structure of the governing body and the methods of the selection of its members.

(2) Minutes of meetings of the governing body and of the members.

(3) An organizational chart for the entire organization.

(4) Written policies and procedures designed to safeguard the health and safety of patients and staff. These policies and procedures shall be reviewed and updated annually. At a minimum the policies shall address:

(a) Selection of personnel and the qualifications for each position. A job description for each position must be included in the administrative records.

(b) Employee health policies that assure employees are free of communicable disease.

(c) Release of information to another facility, agency, or health care provider.

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- (d) Obtaining informed consent.
- (e) Services which the program provides.
- (f) Smoking on the premises. Such policies shall assure the comfort of all patients including patients in waiting areas. In the case of a program operated by a health care facility licensed by the Department, said program shall comply with any regulations concerning smoking that are applicable to such facility.
- (g) Informing patients of the admission criteria, services available, and third party coverage and personal charges.
- (5) Personnel records for each employee, including evidence of any required license or registration number; documentation of any specialty certification, education and job experience.

143.008: Emergency Transfer and Referral

- (A) Each program shall have a written plan and procedure for the emergency transfer including the transport of patients.
- (B) Whenever a program refers a patient to another facility, agency, or health care provider, with the written consent of the patient, it shall send a copy of relevant portions of the program's record on the patient to such facility, agency, or provider.

143.009: Staff

(A) Staff Responsibilities and Qualifications.

(1) Medical Director.

- (a) Each program shall employ, or otherwise retain through a written agreement for services, a physician to serve as medical director. The medical director shall be responsible for establishing all medical protocols, policies and procedures, ensuring the achievement and maintenance of quality standards of medical care, for overall patient care including participation in patient treatment planning meetings and for consultation with program personnel and referring physicians.
- (b) The medical director shall be a physician who is a board certified cardiologist or is board certified in internal medicine or family practice and shall have recent clinical experience in caring for cardiac patients and experience in exercise testing and cardiac rehabilitation.
- (c) The medical director shall be currently certified in advanced cardiac life support by the American Heart Association.

(2) Registered Nurse.

- (a) Each program shall employ a registered nurse who shall collaborate with the Medical Director and Program Director in the operational and clinical aspects of the program.
- (b) Primary responsibilities of the registered nurse shall include, but not be limited to: functional assessment of patients, patient education, participation in establishing and monitoring exercise therapy, EKG telemetry monitoring, provision of emergency care and maintenance of, regular, ongoing communication with the patient's referring physician.
- (c) The registered nurse shall hold a baccalaureate degree or higher in nursing. This nurse shall have experience in cardiac intensive care or other intensive care and in cardiac risk factor intervention and exercise prescription and exercise testing. He/she shall be currently certified in advanced cardiac life support by the American Heart Association. The requirement for the baccalaureate degree shall be waived for any person functioning in a cardiac rehabilitation program on the effective date of these standards.

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(3) Program Director.

(a) Each program shall designate a program director who shall be responsible for the clinical services provided by the program, including the accurate implementation of medical policies and procedures with emphasis on close adherence to exercise prescription and maintenance of safety standards; who supervises the staff and directs all facets of the program, coordinates patient care and who is responsible for the administration aspects of the program.

(b) The program director shall either be a physician meeting the qualifications of the Medical Director as prescribed above or a registered nurse meeting the qualifications of the Registered Nurse as prescribed above except that such nurse shall hold a baccalaureate or higher degree in nursing, or an individual who hold a baccalaureate or higher degree in an allied health field. The Medical Director or the Registered Nurse may also serve as the Program Director if he/she can adequately carry out the duties of both positions. The program director shall have recent previous experience or education in the organization and administration of a cardiac rehabilitation program.

(4) Exercise Therapist.

(a) Each program shall employ, or retain through a written agreement for services, an exercise therapist. The exercise therapist shall be responsible for providing consultation to program staff and advising and/or implementing the exercise component of the program and participating in the patient/family education program services.

(b) The exercise therapist shall be a registered physical therapist or an individual who holds a baccalaureate or higher degree in an exercise science. Such individuals shall have experience in cardiac rehabilitation, EKG monitoring, exercise prescription and exercise testing.

(c) The exercise therapist shall be currently certified in basic life support by the American Heart Association or the American Red Cross.

(5) Dietitian.

(a) Each program shall employ, or otherwise retain through a written agreement for services, a dietitian who shall provide or supervise nutritional counseling services to the patient/family and assist program staff in monitoring patient progress towards nutritional goals.

(b) A dietitian responsible for nutritional counseling services shall be registered or eligible for registration by the American Dietetic Association.

(6) Counselors.

(a) The cardiac rehabilitation program shall employ, or otherwise retain through a written agreement for services, at least one psycho/social counselor. Counseling services shall assist patients in adjusting to illness.

(b) Counseling services shall be provided by qualified professional staff who have experience working in a medical care setting and who are licensed and/or registered in accordance with state law.

(7) Occupational Therapist.

(a) If occupational therapy services are provided, the services shall be provided by and supervised by a registered occupational therapist. Occupational therapy services not directly provided by a registered occupational therapist shall be provided by certified occupational therapy assistants.

(b) Responsibilities of the occupational therapist may include but not be limited to: instruction in energy conservation, activity guidelines, pacing and development of coping strategies for stress management.

(8) Pharmacist.

Each program shall have available at least on a consultant basis the services of a registered pharmacist to advise program staff on drug usage, dosage and effects.

(B) Health Care Staff.

Each program shall retain sufficient qualified professional health care staff to render adequately and appropriately to each patient's needs the services the program holds itself out as providing. Professional health care staff shall be registered or licensed as required by law. They shall comply with the regulations of their registration or licensing boards.

143.010: Treatment Planning

- (A) A written treatment plan based on subjective and objective evaluations as documented in the patient record shall be developed for each patient by a multidisciplinary team of staff involved in the patient's care including the registered nurse and medical director.
- (B) The treatment plan shall include a problem list and established patient goals that are based on the individual patient's risk factor profile, functional capacity, potential for improvement and the patient's personal goals.
- (C) The written plan to achieve goals shall include the specific intervention for each risk factor, and specific exercise prescription based on recent symptom-limited exercise tolerance test.
- (D) Treatment plans shall be reevaluated as necessary but at least prior to advancement to Phase III.
- (E) Upon completion of the Phase III Cardiac Rehabilitation component, a discharge evaluation of the patient shall be made by the nurse and/or program coordinator with the participation of the patient. The discharge evaluation shall be based on subjective and objective measurements, as documented in the patient's record, to identify progress towards goals and to establish ongoing maintenance goals.

143.011: Required Program Components/Services

The following components/services shall be available to a cardiac rehabilitation participant either in a group or individual format and, where possible and appropriate, the family shall be included:

(A) Participant/Family Education Program Services.

- (1) Educational programs shall be developed that address:
 - The nature of cardiovascular disease
 - Management of cardiovascular disease
 - Prevention of cardiovascular disease
- (2) All educational program offerings shall have an established curriculum developed by a multi-disciplinary team comprised of the appropriate professionals. The curriculum shall include objectives, program outline, and plan for program evaluation.
- (3) The education components/services shall be based on the participant's problems and goals for the program.
- (4) The program shall emphasize self-assessment skills and self-help strategies.

(B) Risk Factor/Lifestyle Modification Program Services.

- (1) Risk factor/lifestyle modification programs shall be developed for each of the following risk factors that have been identified for the patient:
 - Smoking
 - Hypertension
 - Abnormal lipid profile
 - Obesity
 - Stress
 - Sedentary lifestyle
 - Glucose Intolerance
- (2) All risk factor/lifestyle modification program offerings shall have an established curriculum developed by a multi-disciplinary team comprised of the appropriate professionals. The curriculum shall include objectives, program outline, and plan for program evaluation.
- (3) The programs shall address the necessary knowledge, attitude and skills to facilitate behavior change.

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(C) Therapeutic Exercise Program Services.

(1) The therapeutic exercise shall be based on a physician's written exercise prescription and shall be approved by the medical director or other physician designated by the medical director. The physician's prescription shall specify exercise intensity. The exercise sessions shall include:

- Warm up
- Aerobic exercise
- Cool down

(2) All patients shall have an individualized written exercise program of activity which includes:

- Type of exercise
- Intensity
- Duration
- Frequency
- Progression of home activity and exercise.

(3) Phase II exercise shall be aimed at the prevention of deconditioning until such time as a symptom limited exercise tolerance test can be safely performed.

(4) Phase III exercise shall address exercise conditioning and shall be based on an exercise prescription established from a symptom-limited exercise tolerance test.

(D) Counseling Services.

(1) Psychosocial support and vocational counseling services shall be available on site or through an affiliation agreement. As appropriate, patients shall be referred for therapeutic mental health services.

(2) In addition, the program shall maintain a resource manual of available community counseling services.

143.012: Patient Records

(A) Each program shall keep in one centralized location on its premises records indicating all the services rendered to patients. Records shall contain sufficient information to justify the services and to document the results accurately.

(B) Each patient shall have a single integrated record. Each entry into each patient record shall be dated and authenticated by the staff member making the entry, indicating name and title. Each page of each patient's record shall have two unique forms of identification. The record with respect to each patient shall include the following:

- (1) Patient's name, date of birth, sex, home address and telephone number; name, address and telephone number of referring physician and sponsor or responsible party, if any.
- (2) Physician referral.
- (3) Report of medical history and physical examination upon initiation of therapeutic exercise program component.
- (4) Assessments, *i.e.* nursing assessment, psychosocial assessment, nutritional assessment and musculo/skeletal assessments.
- (5) Report of any diagnostic tests (exercise tolerance test, Holter, echocardiogram, coronary catheterization, blood tests, etc.
- (6) Discharge summary from most recent hospitalization.
- (7) Report of most recent electrocardiogram.
- (8) Informed consent for treatment.
- (9) Date of each patient visit with program staff.
- (10) Progress notes which include documentation of progress toward goals of the treatment plan.
- (11) Documentation that progress reports were communicated to the referring physician on a regular basis.

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- (12) Orders for any medication, test, or treatment.
- (13) Records of any administration of medications, treatment, or therapy.
- (14) Maximal symptom limited exercise tolerance test prior to Phase III.
- (15) Discharge evaluation.

(C) Each program shall maintain patient records under lock or code and use them in a manner to protect the confidentiality of the information contained therein. Printed copies of electronically stored records shall be disposed of in a manner which assures the confidentiality of patient information.

143.013: Required Facilities, Equipment and Safety Precautions and Procedures for Phase II and Phase III Programs

Facilities and equipment necessary for the delivery of Phase II and Phase III components of the cardiac rehabilitation program shall be readily available for use.

(A) Monitoring During Exercise Therapy Sessions During Phase II and Phase III Programs.

- (1) Continuous electrocardiographic monitoring equipment shall be available for use with new participants and for periodic checks as deemed necessary by the supervising personnel.
- (2) The medical director or his/her designated physician shall be present on the premises during exercise therapy sessions unless the premises is covered by a licensed hospital's medical emergency response team. The designated physician shall be qualified to respond to cardiac emergencies and be currently certified by the American Heart Association in Advanced Cardiac Life Support (ACLS).
- (3) At least one R.N. certified in Advanced Cardiac Life Support by the American Heart Association shall be in attendance at each exercise session in order to monitor patients.
- (4) Where Phase III patients are exercising there shall be in attendance a minimum ratio of one professional staff member to five patients and at least two staff members on the premises.
- (5) Participants shall be instructed in a method to monitor their own exercise intensity (heart rate, perceived exertion, symptoms).

(B) Emergencies/Cardiopulmonary Resuscitation.

- (1) All health care personnel in attendance at the exercise sessions shall be certified in Basic Life Support by the American Heart Association.
- (2) There shall be a written protocol for medical emergencies. There shall be periodic review and drill of this protocol by the staff frequently enough to maintain proficiency during emergencies and in all instances at least on a quarterly basis. A written record of the drills shall be maintained.
- (3) Emergency instructions shall be posted in the exercise area.
- (4) Emergency drugs and equipment for initiation of Advanced Cardiac Life Support (as stipulated by the program's policy) shall be readily available on-site during all exercise sessions. Such drugs shall be accessible only to authorized persons. Expired drugs and sterile supplies shall be removed from storage.

At a minimum emergency supplies shall include:

- (a) Portable defibrillator with "quick" look capabilities
- (b) Oxygen tank with regulator and mask
- (c) Suction and intubation equipment
- (d) Emergency drugs and intravenous equipment
- (e) Blood pressure cuff and stethoscope
- (f) Sublingual nitroglycerin
- (g) Timing device which times to the second

(C) Environmental and Physical Plant Considerations.

- (1) Each program shall maintain its physical facilities in good repair, in a safe, comfortable and sanitary state, free from dirt, vermin, solid waste and objectionable odors.

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- (2) Environmental conditions shall be consistent with written protocols established by the program that reflect safe environmental conditions.
- (3) Drinking water shall be readily available at exercise sessions.
- (4) Each program shall provide adequate space and equipment for reception and waiting areas, for administrative staff offices, and for the storage of patient records.
- (5) Each program shall provide conveniently located handwashing and toilet facilities adequate for patients and personnel. A soap dispenser disposable towels or electronic hand dryers, and a waste receptacle shall be provided at each handwashing sink.
- (6) Each program shall provide all rooms which do not have direct access to the outside, with satisfactory mechanical ventilation.
- (7) Each program shall provide storage space adequate and suitable for equipment and bulk office supplies.

(D) Preventive Maintenance.

- (1) A written preventive maintenance program shall be established and implemented to insure that all equipment is maintained in safe and proper working order.
- (2) A maintenance check shall be regularly performed on all mechanical and electronic medical equipment.
- (3) Electronic equipment shall be properly grounded and calibrated consistent with manufacturer's recommendations or other generally accepted standards.

143.014: Serious Complaint Procedure

Each program shall develop a written procedure that assures prompt and complete investigations of all serious complaints which are filed. The procedure shall include, at a minimum, the following provisions:

- (A) Designation of a member of the program's administration as the person responsible for overseeing the investigation of serious complaints lodged;
- (B) Establishment of a reporting procedure which assures that the designated administrator will receive within one day from staff, in writing, reports of serious complaints;
- (C) Development by the designated administrator of a written process of investigation which shall include the following:
 - (1) A process of fact-gathering that he will utilize, including provision for interviewing of a patient complainant;
 - (2) Creation of a complaint file that includes the original report of complaint, progress reports as investigation is carried out and outcome of investigation including action taken, if any;
 - (3) Notification of the complainant of the outcome of the investigation.

143.015: Evaluation of Quality

- (A) Each program shall establish an organized, comprehensive quality assurance program that is adequate to regularly review and evaluate the quality and appropriateness of care provided. The quality assurance program shall:
 - (1) be defined in writing;
 - (2) identify an individual to be responsible for the implementation and continuity of the program;
 - (3) be re-evaluated at least annually; and
 - (4) describe the mechanisms in effect to identify and resolve problems.
- (B) The findings of the program shall, as appropriate, be utilized in the revision of program policies and procedures.

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(C) The medical director and rehabilitation team members shall participate in the review process.

(D) Each program shall maintain program statistics.

143.016: Exercise Testing

Cardiac rehabilitation programs that conduct exercise tolerance testing directly shall meet the minimum standards for exercise testing laboratories developed by the American Heart Association.

REGULATORY AUTHORITY

105 CMR 143.000: M.G.L. c. 175, § 47D; M.G.L. c. 176A, § 76; M.G.L. c. 176B, § 4F;
M.G.L. c. 176G, § 4.

NON-TEXT PAGE